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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/787,658	03/20/2001	Chicko Kitada	2549US0P	4776
23115	7590	01/05/2004	EXAMINER	
TAKEDA PHARMACEUTICALS NORTH AMERICA, INC INTELLECTUAL PROPERTY DEPARTMENT 475 HALF DAY ROAD SUITE 500 LINCOLNSHIRE, IL 60069			LANDSMAN, ROBERT S	
			ART UNIT	PAPER NUMBER
			1647	

DATE MAILED: 01/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/787,658

Applicant(s)

KITADA ET AL.

Examiner

Robert Landsman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 November 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,26 and 28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,26 and 28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. Formal Matters

- A. The Amendment filed 11/03/03 has been entered into the record.
- B. Claims 1-28 were pending in this application. Claims 2-25 and 27 have been cancelled. Therefore, claims 1, 26 and 28 are pending and are the subject of this Office Action.
- C. All Statutes under 35 USC not found in this Office Action can be found, cited in full, in a previous Office Action.

2. Specification

- A. The amendments to the specification based on mistakes in translation of WO 00/18793 have been acknowledged.

3. Claim Objections

- A. All claim objections have been overcome in view of Applicants' cancellation of, or amendment to, the rejected claims.

4. Claim Rejections - 35 USC § 101

- A. Claims 1, 26 and 28 remain rejected for the reasons already of record on page 3 of the Office Action dated 7/3/03. Applicants argue that The applicants clearly state that the invention is useful for treating AIDS and HIV infection and that subsequently published work clearly demonstrates, and the Examiner acknowledges, that the peptides of the present invention are useful for treating HIV infection and AIDS (J. Virol Dec 2000; 74(24) pages 1 1972-6). Applicants further argue that it is not reasonable to assert that the inventors did not have a credible utility in mind (so as to prejudice the actual conception of the INVENTION), when their subsequent work demonstrated the asserted utility. These arguments have been considered, but are not deemed persuasive. First, though the specification states that this protein may be used to treat AIDS, it appears, respectfully, that this was listed as an attempt to cover all bases. This can be best understood by realizing that the discussion of treating HIV/AIDS was one condition listed among dozens of diseases purported to be treated by the claimed compound. As seen on pages 47-48 of the specification, Applicants state that these peptides are identified as ligands by G protein-coupled receptor proteins expressed in the central nervous system, the circulatory system, the heart, immune system, digestive system, metabolic system, or the reproductive system and can be used as therapeutic or

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prophylactic drugs against disorders such as: dementia including dementia associated with senile dementia, cerebrovascular dementia, dementia associated with retroplastic diseases of the systemic degeneration type (e.g. Alzheimer's disease, Parkinson's disease, Pick's disease, Huntington's disease), dementia associated with infective diseases (e.g. slow virus infections such as Creutzfeldt-Jakob disease), dementia associated with endocrine disease, metabolic disease or toxic disease (e.g. hypothyroidism, vitamin B12 deficiency disease, alcoholism, and intoxication with various drugs, metal or organic compound), dementia associated with neoplastic diseases such (e.g. brain tumor), and dementia associated with traumatopathy (e.g. chronic subdural hematoma); depression, attention deficit hyperactivity disorder (minimal brain dysfunction) syndrome; disturbance of consciousness; anxiety disorder; schizophrenia; phobia, growth hormone secretion disorder (e.g. gigantism, acromegaly), hyperphagia, polyphagia, hypercholesterolemia, hyperglyceridemia, hyperlipidemia, hyperprolactinemia, diabetes (e.g. diabetic complication, diabetic nephropathy, diabetic neuropathy and diabetic retinopathy); cancer (e.g. breast cancer, lymphatic leukemia, lung cancer, bladder cancer, ovarian cancer and prostate cancer), pancreatitis, renal diseases (e.g. chronic renal failure, nephritis); Turner's syndrome; neuropath; rheumatoid arthritis; spinal cord injury; transient ischemic attack; amyotrophic lateral sclerosis; acute myocardial infarct; spinocerebellar degeneration; fracture; injury; atopic dermatitis, osteoporosis, asthma; epilepsy; infertility; arteriosclerosis; emphysema pulmonum; pulmonary edema or hypogalactia. Also they can be applied as an agent that improves the nutritional state and a vasopressor that are used post-operatively. In addition, the peptides of the present invention can be used as therapeutic or prophylactic drugs against AIDS (Acquired Immune Deficiency Syndrome) or the like.

Nowhere in the specification was it made clear that Applicants were aware that the compounds of the present invention could realistically be used to treat HIV/AIDS, nor have Applicants provided any data or examples in the specification to support such an assertion.

5. Claim Rejections - 35 USC § 112, first paragraph - enablement

A. Claims 1, 26 and 28 remain rejected under 35 USC 112 for the reasons already of record on page 4 of the Office Action dated 7/3/03 as well as for the reasons given in the above rejection under 35 USC 101. Applicants argue that the claimed invention is enabled because it has utility as argued previously. Applicants' arguments have been fully considered, but are not found to be persuasive for the reasons discussed above.

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B. Claims 26 and 28 remain rejected under 35 USC 112, first paragraph, for the reasons already of record on page 4 of the Office Action dated 7/3/03. Applicants did not address this argument.

6. Claim Rejections - 35 USC § 112, first paragraph -- written description

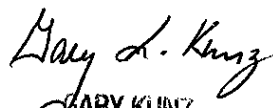
A. Claims 26 and 28 remain rejected under 35 USC 112, first paragraph, for the reasons already of record on page 4 of the Office Action dated 7/3/03. Applicants argue that claims 26 and 28 are ultimately dependent upon claim 1, which had been previously amended to limit the scope of the claim to peptides having a particular amino acid sequence, and is now more clearly stated. This argument has been considered, but is not deemed persuasive. As seen in the above rejection under 35 USC 101, Applicants have listed on pages 47-48 of the specification a laundry list of diseases purported to be treated by the claimed peptides. Though claim 1 recites specific peptide sequences, there is no adequate written description as to what diseases can be treated by these peptide, other than a laundry list.

7. Claim Rejections - 35 USC § 112, second paragraph

A. The rejection of all claims under 35 USC 112, second paragraph, has been withdrawn in view of Applicants' amendment to the claims to remove the formula in claim 1.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

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Advisory information


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (703) 306-3407. The examiner can normally be reached on Monday - Friday from 8:00 AM to 5:00 PM (Eastern time) and alternate Fridays from 8:00 AM to 5:00 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Fax draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Robert Landsman, Ph.D.
Patent Examiner
Group 1600
December 24, 2003


GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600